REMARKS

Applicant would like to thank the Examiner for taking the time to discuss the subject case the afternoon of August 13, 2008 in which applicant's representative and the Examiner discussed teachings of cited art.

Claims 1 to 52 were originally filed. Claims 16, 30 and 32 to 52 have previously been canceled and claims 53 to 68 were added. Accordingly, claims 1 to 15, 17 to 29, 31 and 53 to 68 remain pending in the case.

The Examiner states that the application contains patent application numbers that will have to be updated upon being allowed or abandoned. Applicant believes all application numbers currently needing to be updated as of the filing of this Response have been updated in applicant's paper filed January 22, 2008.

The Examiner rejects the claims under 35 USC 112, first paragraph. This is an enablement rejection. The Examiner states that the specification does not reasonably provide enablement for any "tissue specific promoter" or a "heterologous polypeptide... ...optimized for codon usage by an avian". Applicant traverses the rejection.

Applicant believes that "tissue specific promoter" and "heterologous polypeptide... ...optimized for codon usage by an avian" are fully enabled by the specification as discussed in applicant's Response filed on January 22, 2008.

The Examiner also states that the specification does not reasonably provide enablement for a transgene comprising "at least two nucleotide sequences each encoding a heterologous polypeptide," "that form a multimeric protein," that "specifically bind a selected ligand," that is an "antibody," and using BAC to obtain transgenic avians. Applicant traverses the rejection.

The second sentence of Example 38 at page 108 describes the injection of two OMC24 derived expression vectors carrying light and heavy chains cDNAs of an IgG1 kappa monoclonal antibody (i.e., "at least two nucleotide sequences each encoding a heterologous polypeptide"). The paragraph beginning at the bottom of page 108 and spanning to page 109 describes that the human monoclonal antibody (hMab) purified from egg white was captured in microplates wells coated with the antibody's target antigen and the antibody-antigen complexes were quantitated using isotype-specific secondary antibody conjugated with alkaline phosphatase. The ability of the hMab isolated from egg white to bind its target antigen (i.e., a multimeric protein which binds a selected ligand that is an antibody) is similar to that of the same hMab produced in mammalian cells, as demonstrated by the results of ELISA fluorometric assays shown in Figure 29, as is understood in the art. Accordingly, since "at least two nucleotide sequences each encoding a heterologous polypeptide," "that form a multimeric protein," that "specifically bind a selected ligand," that is an "antibody" is described in the specification, claims 11, 12, 13 and 14 are enabled.

OMC24 is a BAC vector containing an ovomucoid gene expression controlling region and is shown in and Fig. 24 (SEQ ID NO: 42), as is stated in the description of Fig. 24 at page 21 of the specification. Construction of the two BAC vectors is described in Example 37. Therefore, the specification enables the use of BACs in accordance with the invention and claim 15 is allowable.

The Examiner rejects claims under 35 USC 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The specific rejections are as follows

The Examiner states that claim 6 is indefinite because the metes and bounds of a "tissue specific promoter" are not defined in the specification or the art at the time of filing. Applicant disagrees with the rejection. A search of the USPTO patent database for "tissue specific promoter" in US patents issued between January 1, 1985 and October 1, 2003, identifies more than 1400 patents. Accordingly, the meaning of "tissue specific promoter" was well known in the field of molecular biology at the time of filing.

The Examiner states that claim 9 is indefinite because the metes and bounds of a coding sequence that is "optimized for codon usage by an avian" are unclear and that the metes and bounds of such coding sequences cannot be envisioned, i.e., the structure of such coding sequences and the process used to optimize such coding sequences cannot be envisioned. Applicant disagrees with the rejection. A search of the USPTO patent database for patents containing "codon optimized" and "optimized for codon usage" and "codon optimization" and "optimized for codon usage" identified more than 160 patents. Accordingly, the meaning of "optimized for codon usage by an avian" was well know in the field at the time of filing and therefore methods to optimize for codon usage in a specific avian could easily be envisioned by a practitioner of ordinary skill in the field of molecular biology at the time of filing.

The Examiner rejects claims 1-14, 18-22, 25-27 and 31 under 35 USC 103(a) as being unpatentable over Ivarie et al, US Patent No. 6,730,822 (Ivarie) in view of Tanaka. Applicant traverses the rejection.

Tanaka goes into little detail in explaining specifics regarding the ovum transfer experiment. Applicant at best can only speculate on the specifics of Tanaka such as how the plasmids were introduced into the embryos in Tanaka. Accordingly, applicant cannot determine why Tanaka did not produce a viable transgenic avian hatchling. However, one thing that is clear is that the preliminary work of Tanaka was a failure. Therefore, Tanaka discourages or teaches away from producing transgenic avians by the introduction of DNA into avian embryos and implantation of the embryos into recipient hens because the resulting hatchlings in Tanaka did not contain the introduced DNA and accordingly a chick that tests positive for the transgene could not be developed to maturity in Tanaka, as is required in the claims. Accordingly, the combination of Ivarie with Tanaka would not succeed.

The Examiner rejects claims 1-15 and 18-29 under the judicially created doctrine of obviousness type double patenting as being unpatentable over certain copending patent applications.

The Examiner rejects claims 1-15, 18-29 and 53-68 under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 1-17 of US patent No. 7,381,712 in view of the disclosure of '712. Applicant traverses the rejection, because for one thing, the '712 patent was filed after the present application and incorporates by reference the disclosure of the parent to the subject case, i.e., application No. 10/251,364, now issued US Patent No. 7,312,374 (see, column 14, lines 12-15 of the '712 patent). Accordingly, the rejection should be withdrawn.

The Examiner rejects claims 1-15, 18-29 and 53-68 under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 1-23 of copending application No. 11/337,361, in view of the disclosure of '361 and over claims 1-6 of copending application No. 11/376,023, in view of the disclosure of '023 and over claims 1-7 of US Patent No. 6,730,822, in view of the disclosure of '822 and Tanaka. Applicant traverses the rejections.

Each of these double patenting rejections are improper and should be withdrawn because, for example, the '361 application, the '023 application and the '822 patent do not involve the introduction of an injected embryo into a recipient hen and for the reasons provided above for nonobviousness under 35 USC 103(a) for Ivarie in view of Tanaka. Applicant notes that the '361 application and the '023 application are continuation cases of the '822 patent (Ivarie) and contain the same disclosure as the '822 patent (Ivarie).

In conclusion, applicant believes that pending claims 1 to 15, 17 to 29, 31 and 53 to 68 meet the requirements for patentability. Therefore, applicant submits that the presently pending claims are allowable and respectfully requests the Examiner to pass the above-identified application to allowance.

Any fees required for submission of this Response are authorized by applicant. Please deduct any fees and credit any overpayment to Deposit Account No. 501729.

If any issues remain to be addressed in this matter, which might be resolved by discussion, the Examiner is respectfully requested to call applicants' undersigned counsel at the number indicated below.

Respectfully submitted,

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